

REMARKS

Claims 1-31 are currently pending in the above-referenced application, claims 1, 22-24 and 28-41 are canceled by the present amendment. Claims 3 and 12 have been previously allowed. Accordingly, claims 2, 4-11, 13-21 and 25-27 remain for consideration in the present application.

Claims 2, 4-11, 13-21 and 25-27 are rejected under the first paragraph of 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement.

Claims 2, 4-11, 13-21 and 25-27 are rejected under the second paragraph of 35 U.S.C. § 112 as allegedly lacking enablement.

Claims 2, 4-7, 13-16, 19, and 25-27 are currently amended.

This amendment is filed concurrently with a request for continued examination under 37 C.F.R. 1.114 and a proper fee, thus its entry is respectfully requested. Reexamination of the application as amended, reconsideration of the rejections, and allowance of the claims remaining for consideration are respectfully requested.

I. AMENDMENTS TO THE APPLICATION

This response is filed concurrently with a Request for Continued Examination and the proper fee under 37 C.F.R. 1.114, hence entry of the amendments to the application is respectfully requested. As detailed below, the amendments introduce no new matter.

Claims 2, 4-7, 13-16, 19, and 25-27 are currently amended. Claim 2 is amended to claim dependency from independent claim 3, which was previously allowed. Support for amended claim 2 can be found in the specification on p.9 par. 2, p.12 par. 1, and p.14 par. 3.

Claims 4-6 are amended to claim dependency from independent claim 3 which was previously allowed. Support for amended claims 4-6 can be found in the specification on p.34 par. 3.

Claim 7 is amended to clarify the structure of one possible embodiment of a chimeric isoprenoid synthase. Support for amended claim 7 can be found on p.4 par. 2.

Claim 13 is amended to claim dependency from independent claim 12, which was previously allowed. Support for amended claim 13 can be found on p.34 par. 3.

Claim 14 is amended to claim dependency from independent claim 12, which was previously allowed. Support for amended claim 14 can be found on p.34 par. 3.

Claim 15 is amended to claim dependency from independent claim 12, which was previously allowed. Support for amended claim 15 can be found on p.34 par. 3.

Claim 16 is amended to clarify the structure of one possible embodiment of a plant cell comprising a chimeric isoprenoid synthase of the present invention. Support for amended claim 16 can be found on p.4 par. 2.

Claim 19 is amended to clarify the structure of one possible embodiment of a plant cell of the present invention. Support for amended claim 19 can be found on p.4 par. 2.

Claim 25 is amended to claim dependency from independent claim 12, which was previously allowed. Support for amended claim 25 can be found on p.4 par. 2.

Claim 26 is amended to claim dependency from independent claim 12, which was previously allowed. Support for amended claim 26 can be found on p.12 par. 2.

Claim 27 is amended to claim dependency from independent claim 12, which was previously allowed. Support for amended claim 27 can be found on p.15 par. 1.

II. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

1. Written Description:

Examiner has rejected claims 1-2, 4-11, 13-29 and 30-31 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Examiner has stated that the claimed genus allegedly encompasses undisclosed or yet to be discovered sequences as well as the chimeras present in Applicant's specification that synthesize a reaction product not produced by the non-chimeric isoprenoid synthase which broadly reads upon a totally new type of isoprenoid reaction product never produced before.

Examiner has further stated that Applicant allegedly has only described chimeric isoprenoid synthases CH4 and CH10-14 that synthesized 5-epi-aristolochene and vетисpiradiene in varying ratios when transformed into *E. coli*, wherein 5-epi-aristolochene and vетисpiradiene are the natural products of the respective wild type tobacco and henbane enzymes domains of which are comprised within the chimera. Examiner has stated that Applicant allegedly has not described chimeras of isoprenoid synthases that synthesize novel isoprenoids or isoprenoid reaction products not produced by the wild type isoprenoid synthases.

Examiner has further stated that since not all isoprenoid synthases share the same mechanisms, domain requirement for activity, products formed, or relative position of specific domains, thus Applicant allegedly has not described a representative number of chimeric isoprenoid synthases. Examiner has concluded that Applicant allegedly has not described chimeric isoprenoid synthases that synthesize a broad range of isoprenoid products or a broad range of specific isoprenoid products.

To the extent that the amendments to the pending claims do not obviate these rejections, they are respectfully traversed.

Again, all that is required to satisfy the written description requirement of the first paragraph of 35 U.S.C. § 112 is that the patent specification describes the claimed invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed subject matter, to ensure, e.g., that the invention had possession of the claimed subject matter as of the desired priority date. Regents of the University of California v. Eli Lilly & Co., 43 U.S.P.Q. 2d 1398 (Fed. Cir. 1997). In the context of nucleic acids, and by analogy, in the context of proteins encoded by nucleic acids, the recitation of structure for the claimed subject matter need not be great in order to satisfy the written description requirement. “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of a genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” Regents of the University of California, 43 U.S.P.Q. 2d at 1406. Moreover, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in the application by “other appropriate language.” Id.

This basic standard for compliance with the written description requirement under the first paragraph of 35 U.S.C. § 112 is satisfied by the insertion of specific language into the claims reciting a group of chimeric synthases which may be incorporated into the plant cell or transgenic plant. There are sufficient relevant identifying characteristics to meet the written description standard as applied to the amended claims.

The “Guidelines for Examination of Patent Applications Under the 35 USC § 112 par. 1 ‘Written Description’ Requirement,” 66 Fed. Reg. 1099 (January 5, 2001) issued by the United States Patent and Trademark Office, state that the policy goals of the written description requirement are to: (i) clearly convey to the public what was invented; (ii) put the public in possession of what the applicant claims as the invention; and (iii) prevent an applicant from claiming subject matter that was not described in the specification as filed. These policy requirements are met by the amended claims.

Moreover, possession of the claimed invention can be shown by any of: (1) actual reduction to practice; (2) a “clear depiction” of the invention in detailed drawings; or (3) a description of sufficient relevant identifying characteristics. These guidelines are stated in the alternative, so that all three requirements are not required. Only one of these requirements is necessary to satisfy the standard for written description under the first paragraph of 35 U.S.C. § 112. There is actual reduction to practice in terms of the production of several active chimeric synthase molecules, as set forth in Figures 4A, 4B, and 5. The actual reduction to practice goes beyond one specific embodiment. The results recited in the specification indicate that a considerable amount of domain exchange and single-amino-acid mutation is tolerated and is consistent with the enzymatic activity of the chimeric synthases of the invention. This is shown, for example, in Figure 4A, Figure 6, Figure 7, and Figure 8.

The fact that compliance with the written description requirement of the first paragraph of 35 U.S.C. § 112 exists is emphasized by the amendment of the independent claims to include the recitation of a defined group of chimeric synthases which may be incorporated into the plant cell or transgenic plant. This amendment is made for clarity and to further illustrate the degree of structural information recited in the claims.

Moreover, it is well-established that an applicant need not disclose every species encompassed by a claim. In re Angstadt, 190 U.S.P.Q. 214 (C.C.P.A. 1976). The written description requirement cannot force such a requirement, which would be unreasonable. Patents are not production documents.

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976) (“we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims”).

This is clearly not a situation in which a biomolecule sequence is described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence. Here there is a disclosed correlation between the functions of the domains, identity of the chimeric isoprenoid synthases, and the structure of the sequence. See M.P.E.P. § 2163.

Accordingly, in view of the structural features recited, together with the functional characteristics of these chimeric isoprenoid synthases, there is sufficient detail in the specification of this patent application to meet the written description requirement. Therefore, the Examiner is respectfully requested to withdraw this rejection.

2. Enablement:

Examiner has rejected claims 1-2, 4-11, 13-29 and 30-31 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Examiner has stated that the specification, while being enabled for plant cells and plants comprising chimeric variants of sesquiterpene cyclases (e.g. TEAS and HVS and CH4, CH10-CH14) allegedly does not reasonably provide enablement for plant cells and plants comprising any chimeric isoprenoid synthase having an asymmetrically positioned homologous domain that synthesizes a reaction product not produced by the non-chimeric isoprenoid synthase or at least two reaction products not normally produced together by the wild type or non-chimeric isoprenoid synthase. Examiner has further stated that the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

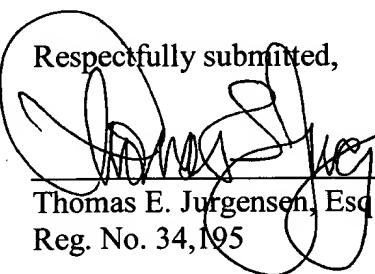
Examiner has also stated that allegedly undue trial and error experimentation would be needed to make and clone a multitude of non-exemplified isoprenoid synthase chimeras and to test them for non-exemplified isoprenoid products not produced by the wild type isoprenoid synthases. Examiner has concluded that the present invention is allegedly not enabled for the scope set forth in the claims.

To the extent that the amendments to the pending claims do not obviate these rejections, they are respectfully traversed.

Examiner has conceded that the specification is fully enabling for plant cells and plants comprising chimeric variants of sesquiterpene synthases such as TEAS, HVS, CH4 and CH10-14. Currently amended claims are fully enabled by the present specification, since the amended claims are directed to plant cells and transgenic plants comprising a nucleic acid molecule encoding a chimeric isoprenoid synthase polypeptide selected from the group consisting of (a) the *tobacco-Hyoscyamus* CH4 chimeric isoprenoid synthase; (b) the *tobacco-Hyoscyamus* CH10 chimeric isoprenoid synthase; (c) the *tobacco-Hyoscyamus* CH11 chimeric isoprenoid synthase; (d) the *tobacco-Hyoscyamus* CH12 chimeric isoprenoid synthase; (e) the *tobacco-Hyoscyamus* CH13 chimeric isoprenoid synthase; and (f) the *tobacco-Hyoscyamus* CH14 chimeric isoprenoid synthase. Therefore, pending claims of the present application as currently amended are believed to meet the enablement requirement of 35 U.S.C. § 112, first paragraph.

In light of the above remarks, the Examiner is respectfully requested to withdraw this rejection as applied to the amended claims. Reexamination and reconsideration in light of the following amendments and remarks is respectfully requested.

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Respectfully submitted,

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